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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/089,449	06/28/2002	Istvan Szelenyi	033285-010	9422

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EXAMINER	
JIANG, SHAOJIA A	
ART UNIT	**PAPER NUMBER**
1617	

DATE MAILED: 08/08/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/089,449	SZELENYI ET AL.	
	Examiner	Art Unit	
	Shaojia A. Jiang	1617	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *16 February 2005 and 17 May 2005*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-4,7 and 8* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-4,7 and 8* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on May 17, 2005 has been entered.

This Office Action is in response to Applicant's request for continued examination (RCE) filed May 17, 2005, and amendment and response to the Final Office Action (mailed November 17, 2005), filed February 16, 2005 wherein claims 1-4 and 7-8 have been amended and claims 5-6 are cancelled; the amendment and response filed May 17, 2005 wherein claims 1-4 and 7-8 have been amended.

Currently, claims 1-4 and 7-8 are pending in this application.

Claims 1-4 and 7-8 as amended now are examined on the merits herein.

Applicant's amendment filed February 16, 2005 with respect to the rejection made under 35 U.S.C. 112 first paragraph for lack of scope of enablement for any β2 adrenoceptor agonists of record stated in the Office Action dated November 17, 2005 has been fully considered and is found persuasive to remove the rejection since the particular β2 adrenoceptor agonists have been recited in the amended claims. Therefore, the said rejection is withdrawn.

Applicant's amendment filed on February 16, 2005 with respect to the rejection of claim 1 made under 35 U.S.C. 112 second paragraph for the use of the indefinite recitation, i.e., "pharmaceutically effective ester" of record stated in the Office Action dated November 17, 2005 have been fully considered and found persuasive to remove the rejection since the indefinite recitation has been deleted from the claims. Therefore, the said rejection is withdrawn.

The following is the new ground(s) of rejection(s).

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1-4 are rejected under 35 U.S.C. 102(b) as being anticipated by Keller et al. (WO 9834595, English equivalent to US 6461591, PTO-892).

Keller et al. discloses a inhalable medicinal aerosol composition or formulation comprising an effective amount of a beta-mimetics which is salbutamol, reproterol, salmeterol, or formoterol, and an effective amount of a corticoids which is loteprednol. See US 6461591, claims 8, 17, 3-4.

Moreover, note that it is well settled that "intended use" of a composition or product, e.g., "in the treatment of ashma brochiale", will not further limit claims drawn to a composition or product, so long as the prior art discloses the same composition

comprising the same ingredients in an effective amount as the instantly claimed. See, e.g., *Ex parte Masham*, 2 USPQ2d 1647 (1987) and *In re Hack* 114, USPQ 161.

Thus, the disclosure of Keller et al. anticipates claims 1-4.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 7-8 are rejected under 35 U.S.C. 103(a) as being unpatentable over Keller et al. in view of Doi, Koji (WO 9831343 of record) and Bjerkec (of record) and van der Molen (of record).

The same disclosure of Keller et al. has been discussed in the 102(b) rejection set forth above.

Keller et al. does not expressly disclose the employment of the inhalable medicinal aerosol composition comprising the combination as instantly claimed in a method for the treatment of ashma brochiale for simultaneous, sequential or separate administration. Keller et al. does not expressly disclose a process for the preparation of the inhalable medicinal aerosol composition therein.

Doi discloses that loteprednol etabonate is known to be useful in a pharmaceutical composition and a method of treating inflammatory conditions or allergy

since loteprednol etabonate has excellent anti inflammatory and antiallergic activities and is value as a drug in an ointment or a liquid form, and loteprednol etabonate is formulated into a long-term stable liquid suspension for nasal administration (see abstract, page 1, 1st and 2nd paragraphs, Examples at page 7-11, calims 1-5).

Ashma brochiale is a known inflammatory condition or allergy.

According to Bjerkec, long-acting β2 agonists, for example, salmeterol and formoterol, are bronchospasmolytics, are used as inhalations in asthma treatment. These long-acting β2 agonists should always be given in combination with corticosteroids. Short-acting β2 agonists, for example, salbutamol, may be given additionally (see abstract; page 587 'Introduction'; page 589, right-hand column, paragraph 4; page 590 'Conclusion'). The corticosteroids indicated include beclomethasone dipropionate, budesonide and fluticasone propionate (see page 588, left-hand column, lïnes 1-2; page 589, right-hand column, line 19).

The clinical study described in van der Molen shows that the symptoms of asthma patients are improved on inhalation of the long-acting β2 agonist, formoterol in addition to inhaled corticosteroids (see abstract; page 536 'Subjects'; page 538 'Discussion'). Van der Molen does not specify the corticosteroids used.

It would have been obvious to a person of ordinary skill in the art at the time the invention was made to employ loteprednol etabonate in combination with reproterol, salmeterol, or formoterol in a method for the treatment of allergies and/or airway disorders such as ashma brochiale for simultaneous, sequential or separate administration.

One having ordinary skill in the art at the time the invention was made would have been motivated to employ loteprednol etabonate in combination with reproterol, salmeterol, or formoterol in a method for the treatment of allergies and/or airway disorders such as ashma brochiale for simultaneous, sequential or separate administration, since both loteprednol etabonate, and reproterol, salmeterol, or formoterol, are known to be useful in a pharmaceutical composition and a method for the treatment of allergies and/or airway disorders such as asthma based on the prior art.

Therefore, one of ordinary skill in the art would have reasonably expected that combining loteprednol etabonate and reproterol, salmeterol, or formoterol both known useful for the same purpose, i.e., treating allergies and/or airway disorders such as asthma, would improve the therapeutic effects for treating the same diseases, and/or would produce additive therapeutic effects in treating the same.

It has been held that it is prima facie obvious to combine two compositions each of which is taught by the prior art to be useful for same purpose in order to form third composition that is to be used for very same purpose; idea of combining them flows logically from their having been individually taught in prior art. See *In re Kerkhoven*, 205 USPQ 1069, CCPA 1980.

Moreover, the teachings of Bjerkec and van der Molen have further clearly provided the motivation for the instant combination, because long-acting β2 agonists, should always be given in combination with corticosteroids according to Bjerkec. The clinical study described in van der Molen shows that the symptoms of asthma patients

are improved on inhalation of the long-acting β2 agonist, formoterol in addition to inhaled corticosteroids. It is noted that loteprednol etabonate is the particular corticosteroid.

Further, the process for preparation of a pharmaceutical composition herein is considered well within conventional skills in pharmaceutical science.

Thus the claimed invention as a whole is seen prima facie obvious over the combined teachings of the prior art.

Applicant's arguments filed February 16, 2005 and May 17, 2005 have been fully considered with respect to the rejection of claims 1-8 made under 35 U.S.C. 103(a) as being unpatentable over Doi, Koji (WO 9831343) and Bjerkec and van der Molen in the previous Office Action dated November 17, 2005 have been considered but are moot in view of the new ground(s) of rejection above.

In view of the rejections to the pending claims set forth above, no claims are allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Examiner Jiang, whose telephone number is (571)272-0627. The examiner can normally be reached on Monday-Friday from 9:00 to 5:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Sreenivasan Padmanabhan, Ph.D., can be reached on (571)272-0629. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

S. Anna Jiang, Ph.D.
Primary Examiner
Art Unit 1617
July 28, 2005